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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,664	05/02/2005	Andrzej Czernecki	POL0005-PCT	5014
36183 7590 01/22/2009 PAUL, HASTINGS, JANOFSKY & WALKER LLP 875 15th Street, NW Washington, DC 20005				
EXAMINER				
TOWA, REINE T				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/506,664

**Applicant(s)**

CZERNECKI ET AL.

**Examiner**

RENE TOWA

**Art Unit**

3736

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3, 4, 8, 10 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 4, 8, 10 and 12-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. This Office is responsive to an amendment filed October 8, 2008. Claims 3-4, 8, 10 & 12-19 are pending. No claim has been amended. No new claim has been added. Claims 1-2, 5-7, 9 and 11 are canceled.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. **Claims 3-4, 8, 10 & 12-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutynowski et al. (US 2001/0039387) in view of Marshall et al. (US 7,087,068).

In regards to **claims 3-4, 8, 10 & 12**, Rutynowski et al. disclose a puncturing device for regulating force of puncture comprising:

a sleeve 1 having a first end and second end, and defining a sleeve axis;

an adjustable push element 2 located at the first end of the sleeve 1;

an adjustable puncture depth element 3 located at the second end of the sleeve 1;

a piston 5 slidably mounted within the sleeve 1, the piston 5 having a wing 12 configured to rest on an edge of the sleeve 1 and prevent the piston 5 from sliding through the sleeve 1 toward the second end of the sleeve 1, and the piston 5 having a puncturing tip 8 on a side of the piston 5 opposite to the first end of the sleeve 1; and

a drive spring 10 within the sleeve 1 and compressed between the push element 2 and the piston 5, and

the drive spring 10 being compressed until the push element 2 presses the piston 5 sufficiently enough to break the wing 12, at which point the drive spring 10 expands and drives the piston 5 toward the second end of the sleeve 1 (see figs. 1-2 & 4; see par 0003 & 0011-0013; see claim 2 of Rutynowski et al.);

wherein the puncture depth element 3 is configured to change an ending position at which travel of the piston 5 in a direction toward the second end of the sleeve 1 is stopped (see par 0013-0014).

In regards to **claim 17**, Rutynowski et al. disclose a device wherein the wing 12 configured to rest on an upper edge 13 of the sleeve 1 (see fig. 4).

In regards to **claim 18**, Rutynowski et al. disclose a device wherein the piston 5 having a second wing 12 configured to rest on an edge 13 of the sleeve 1 (see fig. 4).

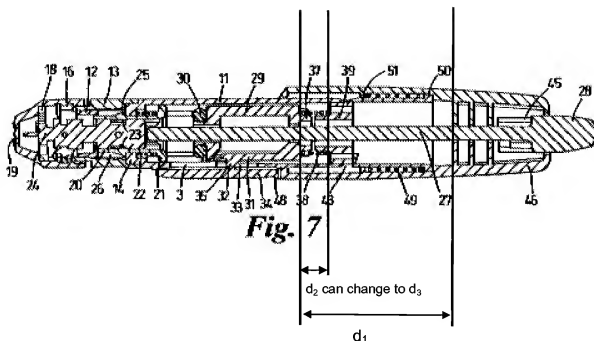
In regards to **claim 19**, Rutynowski et al. disclose a device wherein the piston comprising a central body 5, a push rod 6 on a side of the central body proximate to the first end of the sleeve 1, and a fin 7 on a side of the central body proximate the second end of the sleeve 1, wherein the push element 2 presses on the push rod (see figs. 1-2 & 4).

*Rutynowski et al. disclose a device, as described above, that teaches all the limitations of the claims except for a puncturing force-adjusting member comprising an inwardly directed pair of oblique half-ring, stair-shaped or gradient shaped member, or a drive spring having a length equal to the first distance.*

However, **Marshall et al.** disclose a device for puncturing a patient's skin comprising a push element 44, a turnably mounted puncturing force adjusting member 39 and a piston 29 having a proximal end 37 such that when the device is in a first stable position before the push element 44 is pushed, the drive spring 38 is held within a first distance between a face of the push element 44 and the piston 29,

wherein the puncturing force adjusting member 39 is spaced apart a second distance from the piston 29 when the device is in the first position,

wherein the puncturing force adjusting member 39 changes the second distance so as to adjust a third distance in which the drive spring 38 is compressed between the face of the push element 44 and the piston 29 at the operational position at which the puncturing force adjusting member 39 presses the piston 29, wherein the puncturing force adjusting member 39 changes the second distance without changing the first distance (see abstract; figs. 7-8; col. 3, lines 38-49; col. 4, lines 2-22; see also illustration below).



In regards to **claims 3, 4 & 12**, both Rutynowski et al. and Marshall et al. teach devices for puncturing a patient's skin; since Marshall et al. further teaches a skin pricker wherein the puncturing force can be adjusted in order to cope with skin variations (i.e. from very soft to very tough) (see col. 1, lines 9-18; see abstract), It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the device of Rutynowski et al. to include a puncture force-adjusting member as taught by Marshall et al. in order to achieve a skin pricker wherein the puncturing force can be adjusted in order to cope with skin variations (i.e. from very soft to very tough).

Moreover, Marshall et al. teach a force adjusting member 39 that adjusts the puncturing force by adjusting compressing the proximal end of the drive spring 38 (see

fig. 7); since Rutynowski et al. teach a skin puncturing device wherein the proximal end of the drive spring 10 is in contact with the push element 2 (see figs. 1 & 4), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the device of Rutynowski et al. with a force-adjusting member as taught by Marshall et al. that is mounted at to the push element as claimed in order to compress the proximal end of the drive spring while wherein the proximal end of the drive spring is in contact with the push element. Furthermore, it has previously been held that merely shifting location of parts is not patentable--*See In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).

Even moreover, Marshall teaches a device comprising a spring having a length that is equal to the second distance (see illustration above), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the device of Rutynowski et al. as modified by Marshall et al. with a spring having a length that is equal to the first distance since such a modification would amount to mere design choice that would serve the same purpose of adjusting the force of penetration of the puncturing device; for example, the force adjuster 39 can be made to extend from a face of the push element 44 without changing the principle of operation of the device, thereby causing a longer spring to be used to adjust the force ; furthermore, using a longer spring in the manner proposed above allows the device to adjust the puncturing force over a larger range of possible puncturing forces.

In regards to **claims 13-16**, the Examiner takes Official notice that it is known to provide mechanisms wherein the adjustment involves adjusting the distance between

the adjuster and a moveable piston using either an adjuster comprising a skew slot (see abstract & figs. 1-3 of US 6,530,937), an inwardly directed pair of oblique half-ring members (see abstract, figure 10 & col. 5, lines 7-23 of US 5,613,978; see also figure 2 of Rutynowski et al.), or a stair-shaped member (see fig. 3D & abstract of US 6,558,402), since Marshall et al. teach a device wherein the puncturing force is adjusted by adjusting the distance between a piston 29 and a force adjuster 39 by rotating the force adjuster between a skew slot 43 (see abstract), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the device of Rutynowski et al. as modified by Marshall et al. to include a force adjuster comprising a pair of oblique half-ring members, a stair-shaped or a skew slot member as claimed since such a modification would serve the same purpose of adjusting the distance between the adjuster and a moveable piston.

#### ***Response to Arguments***

4. Applicant's arguments filed October 8, 2008 have been fully considered but they are not persuasive. Applicant argues that the combination of Rutynowski et al. and Marshall et al. fail to teach a device wherein the puncture force is adjusted without adjusting the drive spring. This argument has been considered but has not been deemed persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a device wherein the puncture force is adjusted without adjusting the drive spring) are not recited in the rejected claim(s). Although the claims are interpreted in light of



the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, MPEP, section 2145 (I) clearly stipulates:

The arguments of counsel cannot take the place of evidence in the record. In *re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In *re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

Applicant's assertion of what seems to follow from an alleged inoperability of the combination of the device of Rutynowski et al. and Marshall et al. due to some purported "large forces" is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness. Furthermore, a reliance on supposed "acceptance for the intended use" criteria appears to have no bearing on patentability.

In view of the foregoing, the rejections over Rutynowski et al. and Marshall are maintained.

### **Conclusion**

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./  
Examiner, Art Unit 3736

/Max Hindenburg/

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Supervisory Patent Examiner, Art Unit 3736